SEP 2 7 2001

K012062

510(K) SUMMARY

Manufacturer:	Fixano S.A. Z.A. Les Bruyeres 01960 Peronnas France
Submitted By:	Ferguson Medical Consultant to Fixano S.A.
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories.
Common/Usual Name:	External fixation device, wrist fixator, and others.
Proprietary Name:	PF2
Classification Number:	21 CFR 888.3030/Procode 87 KTT
Substantial Equivalence:	EBI XFIX DFS Wristfix System (K993649) and others.
Device Description:	The device is a balljoint-hinged external fixator capable of rotation and angulation.
Intended Use:	The intended use is similar to that for other external fixators.
Technological Characteristics:	The PF2 device is similar in its intended use to predicate devices and existent methodologies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2001

Mr. Frank Ferguson
C/o Fixano S.A.
Ferguson Medical
P.O. Box 12038
La Jolla, California 92039-2038

Re: K012062
Trade/Device Name: PF2
Regulation Number: 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: II
Product Code: KTT
Dated: May 25, 2001
Received: July 2, 2001

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K012062

Device Name: PF2

Indications For Use:

The Fixano PF2 wrist fixation device is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies, and soft tissue deformities.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012062

Prescription Use ___XX___ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)